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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/594,972 | 06/15/2000 | Ada Goerlach-Graw | BMID 9941 US | 8671 |

32842 7590 11/17/2004

THE LAW OFFICE OF JILL L. WOODBURN, L.L.C.
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EXAMINER

NGUYEN, BAO THUY L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| | 1641 |

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------------|----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/594,972 | GOERLACH-GRAW ET AL. |
| | Examiner Bao-Thuy L. Nguyen | Art Unit 1641 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 September 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 15-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 15-26 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 September 2004 has been entered.

Status of the Claims

2. Claims 15-26 are pending.

Claim Rejections - 35 USC § 112, first paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 15, as amended, is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 15 has been amended to recite that the detection zone is the last zone of the element that allows liquid transport and that it is devoid of a binding reagent that would enable

detection of the analyte. Such a zone is not supported by the specification as originally filed. Nowhere in the specification is there a specific recitation that the detection zone is the last zone that allows liquid transport, nor is there a specific recitation that the detection zone is devoid of a binding reagent.

Applicant asserts that support for this amendment is found in the specification at page 14, and example 1 as well as figures 1-4; however, a review of the specification does not yield proper support. Page 24, Example 1, recites a capture zone made of a fleece composed of 100 % linters, strengthened with two percent by weight Etadurin and having an absorptive capacity of 386 mL/m² and a thickness of 0.41 mm; and further recites that the detection zone is made of the same composition, i.e. a fleece of 100 % linters, strengthened with two percent by weight Etadurin with a thickness of 0.35 mm and an absorptive capacity of 372 ml/m². Even though this description of the detection does not include additional assay reagents, it does not specifically recites that no assay reagents are present. Therefore, because the various zones of the element are made of the same material, and the materials are recited as providing liquid transport between the zones, if the capture zone requires a capture reagent immobilized therein to capture the labeled conjugate in order for detection of the label in this area, it is expected that the detection zone would also have such a requirement, otherwise any labels present would diffuse away from the detection zone, rendering detection moot? Again, no support is found for the recitation of a detection zone being the last zone that allows liquid transport. The specification does not have any specific recitation of this limitation. Furthermore, even if it is true that the detection zone is the last zone of the element that allows liquid transport, this zone is still a liquid transport zone and thus would transport liquid away from the detection zone. In other words, this zone does not concentrate or absorb all liquid and hold it there.

Applicant is required to cancel the new matter in order to obviate this rejection.

Claim Rejections - 35 USC § 112, second paragraph

5. Claims 15-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is confusing with respect to the recitation of a detection zone which is devoid of a binding reagent that would enable detection of the analyte. Nothing else has been recited as enabling the detection of analyte in this zone, therefore, it is unclear how the *detection* zone works.

Claim Rejections - 35 USC § 103

6. The rejections of claims 15-26 under 35 USC 103 are withdrawn in view of the amendment to the claims. However, it is noted that the new limitations are not supported by the specification as originally filed; therefore, the obviousness rejection will be reinstated when the new matter is canceled.

Response to Arguments

7. Applicant's arguments with respect to claims 15-26 have been considered but are moot in view of the new matter rejection.

Conclusion

8. No claim is allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,472,226 B1 discloses a device for detecting analyte where a capture zone has a pore size such that label which is bound to the analyte is concentrated therein enabling their detection.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
11/10/04